REMARKS

Claims 18-31 are pending and stand rejected. Applicants request cancellation of claim 21 without prejudice for possible filing in a divisional application.

Claims 22-31 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over U.S. Patent No. 5,248,310 ("the Barclay patent") in view of U.S. Patent No. 5,785,994 ("the Wong patent"). However, there is no reason to believe that a person of ordinary skill in the art having only the patents before them would have produced a claimed invention, even if one assumes for the sake of argument that such a person would have been motivated to combine the patents' respective teachings.

Indeed, it is apparent that the combination of these teachings would not have produced any claimed invention. The Barclay patent, for example, has been alleged to be relevant for its disclosure of a way to determine the amount of drug remaining in a tablet that includes a drug layer and a polymer layer (Office Action at pages 2-3; Barclay patent at column 5, lines 44-51). According to the Barclay patent, this determination is made through the introduction of different colors into the respective layers, such that the user can readily visualize the relative amount of each layer that is present (Barclay patent at column 5, lines 44-51). The layers of such tablets can be represented as follows:

Drug Layer
Polymer Layer

The Wong patent, in turn, has been alleged to be relevant for its disclosure of tablets having the configuration shown in Figure 3, in which drug-free first layer **18** is positioned adjacent drug-containing second layer **22** which, in turn, is positioned adjacent drug-free third layer **24** (Office Action at page 3 and Wong patent at Figure 3; column 5, lines 21-28; column 9, lines 38-39; column 13, lines 49-63). The layers of such tablets can thus be represented as follows:

Drug-free Layer
Drug Layer
Drug-free Layer

Although the Office Action asserts that those of ordinary skill would have been motivated by the Barclay patent to incorporate coloring agent into any layer of the Wong tablets (Office Action at page 3), such a modification (even if motivated) would not have produced any claimed invention. As will be noted, each of claims 22-31 is directed to tablets that include *two* drug layers, whereas the above-noted Wong tablets include only *one*. Thus, the proposed modification of the Barclay and Wong patents would not have produced any claimed invention. Accordingly, the rejection of claims 22-31 for alleged obviousness is improper and should be withdrawn. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974) (all limitations set forth in a patent claim must be taught or suggested in the prior art to establish a prima facie case of obviousness).

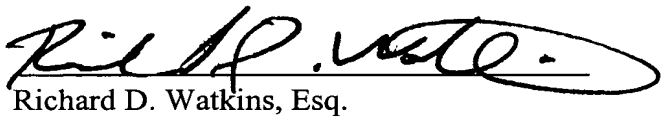
Claims 18-31 stand rejected under 35 U.S.C. §103 as allegedly unpatentable over the Barclay patent in view of the Wong patent and further in view of U.S. Patent Nos. 5,582,838 ("the Rork patent") and 5,422,831 ("the Misra patent"). This rejection lacks basis for at least two reasons. First, the Office Action is mistaken with respect to its assertion that claims 18-31 are "directed to methods of making osmotic tablets" (Office Action at page 4). Claims 22-31 are not directed to methods of making tablets, but tablets themselves.

Second, the Office Action fails to identify any disclosure in the cited references relating to the preparation of tablets having two drug-containing layers. As noted above, the Office Action fails to identify any such disclosure in the Barclay patent or the Wong patent. This deficiency is not remedied by the Rork patent or the Misra patent. The Office Action characterizes the Rork patent as merely teaching the use of colorants in tablets, and the Misra patent as merely teaching methods of using color detectors. Neither these patents nor the Wong or Barclay patents would guide one of ordinary skill in the art to three-layer tablets having two drug layers, or to methods for making such tablets. Although the Office Action asserts that the combination of references would have inspired "further study" of a dosage layer's orientation, it is well settled that "obvious to try" is not the appropriate standard under 35 U.S.C. § 103. *In re O'Farrell*, 853 F.2d 894, 902, 7 U.S.P.Q. 2d 1673 (Fed. Cir. 1988); *In re Deuel*, 51 F.3d 1552, 34 U.S.P.Q. 2d 1210 (Fed. Cir. 1995) (a general incentive does render a particular result obvious). Accordingly, this rejection should be withdrawn.

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Applicants respectfully submit that this application is now in

condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested.

Date: November 4, 2004



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